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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,604	05/16/2001	Brigitte Gicquel	03715.0062-01	2574
22852	7590	11/02/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			KATCHEVES, KONSTANTINA T	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/855,604	<b>Applicant(s)</b> GICQUEL ET AL.	
	<b>Examiner</b> Konstantina Katcheves	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,75-86 and 100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,75-86 and 100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1636

### **DETAILED ACTION**

Claims 1, 75-86 and 100 are pending in the present application.

#### ***Response to Amendment***

The rejection of claims 1, 75-86 and 100 under 35 U.S.C. 112, second paragraph, have been withdrawn in view of Applicant's amendment filed 16 August 2004.

Claims 1, 75, 76, 79, 81-84 and 100 stand rejected under 35 U.S.C. 102(b) as being anticipated by either Gicquel et al. (US 6,248,581 B1) ('581 Patent) or Gicquel et al. (WO 96/07745) (WO '745) for the reasons of record and those set forth below.

Claims 1, 75-86 and 100 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gicquel et al. (FR 2 767 336) ("FR '336") for the reasons of record and those set forth below.

Claims 1, 75, 76 and 79 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 6 of U.S. Patent No. 6,248,581.

#### ***Priority***

The denial of Applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon applications filed in France, FR 97 10404 and FR 97 11325, on 14 August 1997 and 11 September 1997, respectively, stands as set forth in the prior Office action. Applicant argues that a claim for priority in the Oath/Declaration filed on 2 May 2002 to PCT/FR98/01813 has "the same effect, from its international filing date, of a national application filed in the United States" based on 35 U.S.C. 363. As such, Applicant asserts that the present Application is therefore a continuation of US Application 09/485536.

Art Unit: 1636

US Application 09/485536 is the national stage filing of PCT/FR98/01813. Priority to US Application 09/485536 was not claimed in the Oath/Declaration filed and was not asserted in the specification. Patent law 35 U.S.C. 363 is related to the filing of national stage applications and codifies the understanding that the filing date of the national stage application of an international filing is the filing date of the international application. Although the present application claims priority to international application, PCT/FR98/01813, the present application is not the national stage filing of PCT/FR98/01813. Therefore, 35 U.S.C. 363 is not appropriate as a means for asserting that the present application is a continuation of 09/485536.

Applicant also asserts that the prior Application No. 09/485536 was expressly incorporated by reference in the transmittal letter and should thereby be considered for purposes of priority. However, according to MPEP 201.14:

**A. Application NOT Entitled to a Filing Date**

Material needed to accord an application a filing date may not be incorporated by reference. Therefore, if a continuation or divisional application as originally filed incorporates by reference material omitted from the application papers, which is needed to accord the application a filing date, the application will not be entitled to a filing date. A petition under 37 CFR 1.182 and the required petition fee, including an amendment submitting the necessary omitted material, requesting that the necessary omitted material contained in the prior application and submitted in the amendment, be included in the continuation or divisional application based upon the incorporation by reference statement, is required in order to accord the application a filing date as of the date of deposit of the continuation or divisional application. An amendment submitting the omitted material and relying upon the incorporation by reference will not be entered in the continuation or divisional application unless a decision granting the petition states that the application is accorded a filing date and that the amendment will be entered.

Therefore, Applicant's argument is not persuasive. A transmittal letter is not sufficient to provide for the claim that the present application is a continuation of US Application 09/485536.

Moreover, Applicant's amendment of the specification to claim priority to US Application

Art Unit: 1636

09/485536 is outside the time period as determined by the director. See 35 U.S.C. 120 and MPEP

201.11 (quoted below).

(E) For utility or plant applications (including reissues) filed on or after November 29, 2000, benefit claims under 35 U.S.C. 119(e), 120, 121 and 365(c) must be made during the pendency of the application and within the time period set forth in 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If the application is an application filed under 35 U.S.C. 111(a), the benefit claim must be made within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, the benefit claim must be made within the later of four months from the date on which the national stage commenced under ~~35 U.S.C. 371(b)~~ or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and /or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application under 35 U.S.C. 119(e), 120, 121 and 365(c).

Therefore, the amendment filed 16 August 2004 amending the specification to claim benefit to

US Application 09/485536 is objected. Correction is required.

### ***Response to Arguments***

Claims 1, 75, 76, 79, 81-84 and 100 stand rejected under 35 U.S.C. 102(b) as being anticipated by either Gicquel et al. (US 6,248,581 B1) ('581 Patent) or Gicquel et al. (WO 96/07745) (WO '745). Claims 1, 75-86 and 100 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gicquel et al. (FR 2 767 336) ("FR '336").

Applicant argues that each of the cited references are not appropriate under 35 U.S.C. 102(b) because of Applicant's claim for priority to US Application Number:09/485536. Applicant's reason for this assertion have been addressed above and are not persuasive.

Art Unit: 1636

Applicant also argues with regard to WO '745 that WO '745 fails to teach "a coding nucleotide sequences encoding a marker for the activity of promoters." This argument is noted but not found persuasive because WO '745 does teach a marker. In order for a marker to be expressed in a cell it must be operably linked to a promoter. Thus, the marker would inherently show that a promoter is active by the fact that it is expressed. See abstract.

Claims 1, 75, 76 and 79 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 6 of U.S. Patent No. 6,248,581.

Applicant argues that claims 5 and 6 of the '581 patent are not generic to the invention of the instant claims. Indeed this is the case. Applicant is directed to the disclosure of the specification for guidance. It is understood that the disclosure is not generally used in an obviousness double patenting rejection. However, where clarification of the claims is required it is appropriate. According to *In re Vogel* 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970), "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. See MPEP 804. The '581 discloses that the specific embodiments of the claims are drawn to:

Recombinant screening, cloning and/or expression vector characterized in that it replicates in mycobacteria and contains 1) a mycobacteria functional replicon; 2) a selection marker, 3) a reporter cassette comprising a) a multiple cloning site (polylinker) b) a transcription terminator which is active in mycobacteria and is located upstream of the polylinker, and c) a coding nucleotide sequence derived from a gene coding for an expression, export

Art Unit: 1636

and/or secretion protein marker, the nucleotide sequence being deprived of its initiation codon and its regulating sequences. This vector is used for identification and expression of exporter polypeptides, such as the Mycobacterium tuberculosis P28 antigen. See U.S. 6248581, abstract.

This is precisely what is presently claimed in the instant application. Therefore, the double patenting rejection is appropriate.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



JAMES KETTER  
PRIMARY EXAMINER